

**D. REMARKS/ARGUMENTS**

**1. Amendment to the Specification**

The specification has been amended to revise the phrase "proximate end" to "proximal end." No new matter is added by this amendment.

**2. Status of the Claims**

Claims 1-20 are currently pending in the application. Claims 1, 7, and 15 are independent.

Claims 1, 4, 7, and 15 have been amended. No new matter is added by the amendments to claims 1, 4, 7, and 15. Support for these amendments can be found throughout the specification, as discussed in full in sections 2 below.

**3. Rejection of Claims 1 and 4 under 35 U.S.C. § 112**

Claims 1 and 4 stand rejected under 35 U.S.C. § 112, second paragraph, because of the use of the words "adapted to". The Examiner states: "It has been held that the recitation that an element is "adapted to" to perform a function is not a positive limitation but only requires the ability to so perform. It does not constitute a limitation in any patentable sense."

In response, Applicant has amended claims 1 and 4. Claim 1 has been amended to recite that the biocompatible material is flexible enough to conform to the shape of the surface contour of the applicator head. Claim 4 has been amended to recite that the biocompatible material is characterized by an adhesiveness sufficient to allow the radiation shield to be coupled to the applicator head.

Applicant respectfully submits that as a result of these amendments, the above-described rejections of claims 1 and 4 under 35 U.S.C. § 112 have been overcome.

**4. Rejection of Claims 7-20 under 35 U.S.C. § 112**

Claims 7-20 stand rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards

as the invention. In particular, the Examiner states that there is insufficient antecedent basis for the limitation "said area" in independent claims 7 and 15.

Accordingly, Applicant has amended independent claims 7 and 15, so that the limitation "said area" is changed to "said volume." The limitation "said volume" has proper antecedent basis in claims 7 and 15.

Applicant notes with appreciation that although claims 7-20 have been rejected under 35 U.S.C. § 112 second paragraph, claims 7-20 would be allowable if rewritten or amended to overcome the rejections under 35 U.S.C. § 112. Since claims 7 and 15 have been amended to overcome the 35 U.S.C. § 112 rejections, as discussed above, Applicant submits that claims 7 and 15, as well as claims 8-14 dependent on claim 7 and claims 16-20 dependent on claim 15, are now in condition for allowance.

**5. Rejection of Claim 1 Under 35 U.S.C. § 102**

Claim 1 stands rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Pat. No. 5,153,900 to Nomikos et al. ("Nomikos"). Applicant respectfully traverses.

Applicant respectfully submits that Nomikos does not teach or suggest at least the following limitations of amended claim 1: *a radiation shield that includes biocompatible material that can conform to the shape of at least a portion of the surface contour of the applicator head; and a radiation applicator system that includes an applicator head defining a surface having a predefined shape and surface contour.*

Contrary to the Examiner's statement, the item described in Nomikos using the reference numeral 26 is not an applicator head, but rather is a radiation target assembly that is part of the radiation source, not part of the applicator system. See e.g. Nomikos Col. 5 line 68 - Col. 6 line 1 ("Probe 14 is integral with the housing 12 and extends toward a target assembly 26." )(Underlining added.); Nomikos Col. 6, lines 24 – 33 )"The target assembly 26 includes an emission element . . . "; Nomikos Col. 6 line 7 – Col. 7, line 3.

As seen from these cited passages in Nomikos, the target assembly 26 includes x-ray emissive material for generating x-rays when bombarded with electrons. The target assembly 26 has nothing whatsoever to do with an applicator head for an applicator system, and in particular

with any applicator head that defines any surface having a predefined shape and surface contour.

Moreover, nowhere in Nomikos is there any disclosure of a radiation shield made of biocompatible material that can conform to the shape of the surface contour of an applicator head.

It is well established that a prior art reference anticipates a claim only if the reference discloses all the elements and limitations of the claim. If even one element or limitation of the claim is missing, a § 102 rejection fails. See e.g. Kalman v. Kimberly-Clark, 713 F.2d 760, 771, 218 U.S.P.Q. 781 (Fed. Cir. 1983).

Applicant respectfully submits that because Nomikos does not teach, disclose, mention, or suggest at least the above-described limitations of claim 1, Nomikos does not anticipate claim 1 35 U.S.C. § 102 (b).

**6. Rejection of Claims 2-6 Under 35 U.S.C. § 103**

Claims 2-6 stand rejected under 35 U.S.C. § 103 as being unpatentable over Nomikos. Applicant respectfully traverses.

Applicant submits that claims 2-6, which depend on claim 1 and hence include all the limitations of claim 1, are patentable for at least the same reasons (discussed in section 5 above) for which claim 1 is patentable. Specifically, Applicant reiterates that Nomikos does not teach the limitations of claim 1 discussed in section 5 above, for all of the reasons set forth in section 5, and therefore that claims 2-6 (depending on claim 1) are not rendered obvious by Nomikos.

The Examiner has discussed additional limitations of claims 2-6 (e.g., that “the biocompatible material include at least one radiation blocking or absorbing material chosen from the group including tungsten, gold, platinum, rhodium, iridium, tantalum and barium oxide,” that “the biocompatible material including at least one material chosen from the group including urethane, silicone, polyamides, and polystyrenes,” that “at least a portion of the biocompatible material is characterized by an adhesiveness sufficient to allow the radiation shield to be coupled to the applicator head,” that “the biocompatible radiation shield is formed from tungsten filled urethane material,” and that “the biocompatible radiation shield is formed from tungsten filled urethane material.”) Regarding these additional limitations, Applicant respectfully submits that

claims 2-6 are not rendered obvious over Nomikos because nowhere in Nomikos is there any suggestion, teaching, or motivation to modify Nomikos (i.e. the reference on which the rejection is based) to include the further limitations discussed by the Examiner.

As well known, a *prima facie* case of obviousness cannot be established, absent any suggestion, teaching, or motivation to modify a reference (or to combine references). Furthermore, even if Nomikos were modified as suggested by the Examiner, Nomikos would in any case fail to teach all of the elements and limitations recited in claims 2-6, because (as discussed in section 5 above) Nomikos does not teach or suggest at least the following limitations of claim 1: *a radiation shield that includes biocompatible material that can conform to the shape of at least a portion of the surface contour of the applicator head; and a radiation applicator system that includes an applicator head defining a surface having a predefined shape and surface contour.*

Applicant also points out that the Examiner's discussion of the further limitations of claims 2 and 4 is incorrect, because the reference numeral 26 in Nomikos is used to indicate a radiation target assembly, not an applicator head, as discussed above in section 5. Regarding the further limitation of claim 3, Applicant points out that Nomikos col. 7 lines 19-29 does not teach, suggest or mention silicone, polyamides, or polystyrenes. Regarding the further limitations of claims 5 and 6, Applicant points out that nowhere in Nomikos is it taught or suggested that any biocompatible radiation shield be formed from tungsten filled urethane material. In particular, col. 6 lines 20-45 of Nomikos discusses the x-ray target material, which may include tungsten, but which has nothing to do with any radiation shield.

For all of these reasons, Applicant submits that there is no proper basis for a § 103 rejection of claims 2-6, which are not rendered obvious by Nomikos.

7. Conclusion

On the basis of the foregoing amendments, Applicant respectfully submits that all of the pending claims 1-20 are in condition for allowance. A favorable action is therefore earnestly solicited. If there are any questions regarding these amendments and remarks, the Examiner is encouraged to contact the undersigned at the telephone number provided below.

Respectfully submitted,

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